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EXAMINER

FORMAN, BETTY J

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/993,353

Applicant(s)

ELLSON ET AL.

Examiner

BJ Forman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-44, 91, 93-103, 107, 109 and 110 is/are pending in the application.
- 4a) Of the above claim(s) 109 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-44, 91, 93-103, 107 and 110 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **FINAL ACTION**

### ***Status of the Claims***

1. This action is in response to papers filed 11 April 2005 in which claims 1, 3, 13-18, 21-22, 91 and 107 were amended and claim 108 was canceled. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 10 November 2004 are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are discussed below as they apply to the instant grounds for rejection. New grounds for rejection, necessitated by amendment, are discussed.

Claims 1-9, 11-44, 91, 93-103, 107 and 110 are under prosecution.

### ***Claim Rejections - 35 USC § 112***

#### **35 U.S.C. 112: First paragraph, New Matter**

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-9, 11-44, 91, 93-103, 107 and 110 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The term "removable" is added to the newly amended independent Claim 1 from which all other claims depend. The term is used to define the substrate. However, the specification

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fails to define or provide any disclosure to support such claim recitation. The specification, in the paragraph spanning pages 14-15, describes the substrate as having various forms and compositions. However, the passage does not describe a "removable" substrate.

Furthermore, the specification does not teach or describe the meaning or scope of the newly claimed substrate.

The phrase "by technological means" is added to newly amended Claim 3. The phrase is used to define the "secured" information. However, the specification fails to define or provide any disclosure to support such claim recitation. Furthermore, the specification is silent regarding the "means" by which information is provided. Therefore, one of skill in the art would not be appraised of the meets and bounds of the claim.

MPEP 2163.06 notes "If NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "WHEN AN AMENDMENT IS FILED IN REPLY TO AN OBJECTION OR REJECTION BASED ON 35 U.S.C. 112, FIRST PARAGRAPH, A STUDY OF THE ENTIRE APPLICATION IS OFTEN NECESSARY TO DETERMINE WHETHER OR NOT "NEW MATTER" IS INVOLVED. APPLICANT SHOULD THEREFORE SPECIFICALLY POINT OUT THE SUPPORT FOR ANY AMENDMENTS MADE TO THE DISCLOSURE" (emphasis added).

#### **35 U.S.C. 112: Second paragraph, Indefinite**

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 3 is indefinite for the recitation "secured by technological means" because it is unclear whether the recitation is describing a structural element or whether the recitation is describing a method step for making the device.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-9, 11-17, 21-22, 30-43, 91, 96-103 and 107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Virtanen (U.S. Patent No. 6,342,349, filed 21 July 1998) in view of Hammock et al (U.S. Patent No. 6,395,562, filed 4 September 1998).

Regarding Claim 1, Virtanen discloses a device comprising a substrate having a plurality of probe moieties attached to a surface thereof and containing machine readable information relating to the moieties wherein the information is physically associated with the substrate (Abstract; Column 5, lines 14-27 and Column 42, line 67-Column 43, line 58) and further comprising a source of the target moiety. The claimed "source" is broadly consistent with to encompass anyone of the sources disclosed by Virtanen e.g. patient (Column 23, lines 8-13); sample inlet port (Column 53, lines 55-63 and Fig. 20); sample delivery devices (Column 60, lines 41-46); and pipetting robot (Column 63, lines 12-46).

Virtanen disclose the device further comprising a fluidic device for applying target (Column 60, lines 40-46 and Column 63, lines 14-46) an apparatus for measuring interaction characteristics (Column 14, lines 53-67) and a machine whereby the functionality of the device is automated (Column 7, lines 10-59 and Column 59, line 38-Column 60, line 39). Virtanen

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further teach their device uses computerized software for reading and controlling the device before and after assays (Column 15, lines 9-44) which clearly suggests their device is automated, but they do not specifically teach computer-controlled solution application. However, this technique of computer controlled application was well known in the art at the time the claimed invention was made as taught by Hammock et al.

Hammock et al teach a similar device comprising a substrate having readable information, a fluidic device and measuring apparatus and computer for controlling solution application, reading of machine-readable information and characterization of target-probe interaction (Abstract and Column 3, line 56-Column 4, line 6) wherein their automated device performs analysis efficiently and at reasonable costs (Column 2, lines 8-12).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the automation of Hammock et al to the device of Virtanen with a reasonable expectation of success based on the suggestion of Virtanen to do so. One of ordinary skill in the art would have been motivated to do so based on the advantages taught by Hammock et al i.e. an automated device performs analysis efficiently and at reasonable costs (Column 2, lines 8-12).

Regarding Claims 2-4, Virtanen discloses a device comprising a substrate having a plurality of probe moieties attached to a surface thereof and containing machine readable information relating to the moieties wherein the information is physically associated with the substrate (Abstract; Column 5, lines 14-27 and Column 42, line 67-Column 43, line 58) and further comprising a source of the target moiety. Furthermore, Virtanen teach the information encompasses various types of information relating to the attached moieties including patient information, diagnostic information, assay information and interpretive information (Column 15, lines 1-22) which clearly suggests that the information includes customer information, secured information e.g. shipping and/or billing information. Furthermore, Hammock et al who teach a similar device comprising a substrate and readable information also teach that the

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information includes various types of information relating to the attached moieties (Column 2, lines 23-25, Column 3, lines 15-18 and 44-64). This too suggests that the information relating to the moieties includes customer information, secure information and shipping and/or billing information.

However, the courts have stated that non-functional descriptive material does not distinguish a claimed invention over the prior art.

Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. Cf. *In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) (when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability). Common situations involving nonfunctional descriptive material are: a computer-readable storage medium that differs from the prior art solely with respect to nonfunctional descriptive material, such as music or a literary work, encoded on the medium, See MPEP 2106. A combination including printed matter and structure wherein the features of structure are old and the relationship of the printed matter to the structure is old, so that any novelty is in the meaning or significance of the words used in the printed matter, is not patentable as a manufacture in the sense of 35 U.S.C. 101". *Boyle et al. v. Ladd*, 138 USPQ 289 (D.C.D.C. 1963); *Ex parte Gwinn, Jr.*, 112 USPQ 439 (1955); *Conover v. Coe*, 69 App. D.C. 144, 99 F.2d 377, 38 USPQ 309 (1938), and *In re Russell*, 18 CCPA 1184, 48 F.2d 668, 9 USPQ 181 (1931).

Therefore, because the courts have stated that nonfunctional descriptive material encoded on a medium does not distinguish an invention from the prior art and because the prior art teaches the claimed structural components and suggests the instantly claimed customer identity information, secured information and shipping and/or billing information. The instantly claimed devices of Claims 2-4 are obvious in view of the teachings of *Virtanen* and *Hammock et al* and the guidance provided by the courts.

Regarding Claim 5, *Virtanen* discloses the device wherein the information contains the identity of at least one moiety attached to the surface (Column 14, lines 35-67 and Column 45, lines 59-67).

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Regarding Claim 6-8, Virtanen discloses the device wherein the information is analyte-specific information (Column 15, lines 1-22) and analyte-specific information "relates" to analyte attachment processes, analyte experimental conditions and analyte experimental results. As such, Virtanen discloses the device as claimed.

Regarding Claim 9, Virtanen discloses the device wherein the information is digital (Column 3, lines 13-27).

Regarding Claims 11-12, Virtanen discloses the device wherein the information is on a CD or DVD which represents about 1 to 650 megabytes (Column 4, lines 13-35). Therefore, the information on the DC or DVD is represented by about 1 to 650 megabytes as claimed.

Regarding Claim 13, Virtanen discloses the device wherein the information is in a format that is optically readable (Column 5, lines 23-27).

Regarding Claim 14, Virtanen discloses the device wherein the information is in a format that is readable by a fluorescence reader (Column 38, line 65-Column 40, line 58).

Regarding Claim 15, Virtanen discloses the device wherein the information is in a format that is readable by a phosphoimager (Column 38, line 65-Column 40, line 58).

Regarding Claim 16, Virtanen discloses the device wherein the information is in a format that is readable by a compact disc reader (Column 5, lines 13-22).

Regarding Claim 17, Virtanen discloses the device wherein the information is in a format that is readable by a DVD (Column 5, lines 13-22).

Regarding Claim 21, Virtanen discloses the device wherein the information is magnetically readable (Column 38, line 65-Column 39, line 60 and Column 40, lines 17-58).

Regarding Claim 22, Virtanen discloses the device wherein the information is electronically readable (Column 38, line 65-Column 39, line 60 and Column 40, lines 17-58).

Regarding Claim 30, Virtanen discloses the device wherein the moieties comprise an array of biomolecules (Claim 8 and 9).



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Regarding Claim 31, Virtanen discloses the device wherein the biomolecules are nucleotidic or peptidic (Claim 8 and 9).

Regarding Claim 32, Virtanen discloses the device wherein the biomolecules are oligomeric or polymeric (Claim 8 and 9).

Regarding Claims 33-36, Virtanen utilizes the surface for spatially resolved assays (Column 14, line 53-Column 15, line 22) but is silent regarding the density of moieties on the surface. However, Hammock et al teaches the similar device wherein the surface comprises moiety arrays of  $100\mu\text{ m}^2$  which encompasses the claimed about 1,000,000 moieties/ $\text{cm}^2$  (Column 5, lines 11-16, 60-65 and Claim 7) and wherein the dimension is particularly desirable for spatially resolved assays. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the moiety dimension of Hammock et al to the surface of Virtanen and to attach about 1,000,000 moieties per square centimeter thereby providing for spatially resolved assays as taught by Hammock et al (Column 5, lines 60-65) and as desired by Virtanen (Column 14, line 53-Column 15, line 22)

Regarding Claim 37, Virtanen discloses the device wherein the substrate comprises a disk (Column 5, lines 14-27).

Regarding Claim 38, Virtanen discloses the device wherein the substrate comprises a tape i.e. strip (Column 7, lines 51-65).

Regarding Claim 39, Virtanen discloses the device wherein the substrate comprises a well plate (Column 7, lines 51-65).

Regarding Claim 40, Virtanen discloses the device wherein the substrate comprises a slide (Column 7, lines 51-65).

Regarding Claim 41, Virtanen discloses the device wherein the substrate comprises a plurality of surfaces arranged in a three-dimensional structure to which moieties are attached i.e. well plate (Column 7, lines 51-65).

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Regarding Claim 42, Virtanen discloses the device wherein the substrate comprises an additional magnetic medium i.e. labeled moieties (Column 40, line 59-Column 41, line 7).

Regarding Claim 43, Virtanen discloses the device wherein the substrate comprises an additional optical medium i.e. labeled moieties (Column 40, line 59-Column 41, line 7).

Regarding Claim 91, Virtanen discloses the device wherein the information is contained in a discrete region of the substrate surface having the plurality of moieties (Column 15, lines 12-15).

Regarding Claim 96, Virtanen discloses the device wherein the information and the attached moieties exhibit positional correspondence (Column 9, lines 55-59 and Fig. 11C).

Regarding Claim 97, Virtanen discloses the device wherein the substrate has a radial mass distribution that is symmetric about an axis perpendicular to the plane of the substrate (Column 9, lines 44-65 and Fig. 11).

Regarding Claim 98, Virtanen discloses the device wherein the substrate is in the form of a disk (Column 7, lines 51-65).

Regarding Claim 99, Virtanen discloses the device wherein the information is contained in a computer microchip i.e. silicon chip (Column 7, lines 56-59).

Regarding Claim 100, Virtanen discloses the device wherein the information is stored in a medium capable of emitting radiation (Column 13, line 66-Column 14, line 47).

Regarding Claim 101, Virtanen discloses the device wherein the radiation is electromagnetic radiation (Column 13, line 66-Column 14, line 47 and Column 40, line 60-Column 41, line 28).

Regarding Claim 102, Virtanen discloses the device wherein the radiation is a fluorescent medium (Column 13, line 66-Column 14, line 47 and Column 40, line 60-Column 41, line 28).

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Regarding Claim 103, Virtanen disclose the information is on a DC or DVD (Column 5, lines 17-22) and therefore teach the information is "represented" by no less than 1 kilobyte as claimed.

Regarding Claim 107, Virtanen disclose the device wherein the response and data signals are in radioactively detectable/readable form (Column 40, line 59-Column 41, line 7, especially, line 5).

8. Claims 1, 2-9, 11-13, 18-27, 31-32, 37, 39-40, 42-44, 91, 93-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nova et al. (U.S. Patent No. 6,284,459 B1, filed 5 September 1996) in view of Virtanen (U.S. Patent No. 6,342,349, filed 21 July 1998).

Regarding Claim 1, Nova et al. disclose a device comprising a substrate having a plurality of molecule moieties attached to a surface thereof and machine-readable information relating to the molecular moieties wherein the information is contained in a discrete region of the substrate that is noncoplanar with respect to the surface having the plurality of moieties attached thereto (Column 42, lines 46-67 and Fig. 26-27) wherein the machine-readable information contains information relating to the molecule identity, their process of preparation, their batch number, category, physical properties and chemical properties (Column 8, lines 42-47) wherein the substrate comprises a disk i.e. silicon chip (Column 19, line 41-Column 20, line 1) and wherein the device comprises a machine for automated reading and controlling the device (Column 22, lines 37-56).

Nova et al are silent regarding a device for delivering the target. However, Virtanen et al teach the similar device comprising the claimed source e.g. sample inlet port (Column 53, lines 55-63 and Fig. 20); sample delivery devices (Column 60, lines 41-46); and pipetting robot (Column 63, lines 12-46).

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It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the target source of Virtanen to the device of Nova et al for the obvious benefits of providing ready access for the target to the substrate as illustrated by Virtanen (Fig. 20 and 44).

Regarding Claims 2-4, Nova et al. disclose the device comprising machine-readable information i.e. OMD (Column 19, lines 31-40 and Column 42, lines 46-67). Virtanen teach a similar device comprising a disk and machine readable information wherein the information encompasses various types of information relating to the attached moieties including patient information, diagnostic information, assay information and interpretive information (Column 15, lines 1-22) which clearly suggests that the information includes customer information, secure information and shipping and/or billing information.

However, the courts have stated that non-functional descriptive material does not distinguish a claimed invention over the prior art. Because the courts have stated that nonfunctional descriptive material encoded on a medium does not distinguish an invention from the prior art and because the prior art teaches the claimed structural components and suggests the instantly claimed customer identity information, secured information and shipping and/or billing information. The instantly claimed devices of Claims 2-4 are obvious in view of the teachings of Nova et al and Virtanen.

Regarding Claim 5, Nova et al. disclose the device wherein the machine-readable information comprises the identity of at least one of the moieties attached to the surface (Column 8, lines 42-47).

Regarding Claim 6, Nova et al. disclose the device wherein the machine readable information comprises information relating to a process by which the moieties are attached i.e. process of preparation (Column 8, lines 42-47).

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Regarding Claim 7, Nova et al. disclose the device wherein the machine-readable information comprises information relating to experimental conditions (Column 73, lines 40-54).

Regarding Claim 8, Nova et al. disclose the device wherein the machine-readable information comprises information relating to experimental results (Column 73, lines 40-54).

Regarding Claim 9, Nova et al. disclose the device wherein the machine-readable information is digital (Column 73, lines 45-50).

Regarding Claims 11-12, Nova et al are silent regarding the substrate containing no less than 1 megabyte (Claim 11) and about 1 to 650 megabytes (Claim 12) of machine-readable information. However, machine readable disk substrates comprising 1 to 650 megabytes of data were well known in the art at the time the claimed invention was made as taught by Virtanen (Column 4, lines 13-35) who teach that the that disk device provides for high density information and analyte detection utilizing disk readers known in the art (Column 5, lines 14-27 and Fig. 11). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the megabyte of data taught by Virtanen to the disk of Nova et al for the obvious benefits of providing a large amount of data readable utilizing readily available disk readers as taught by Virtanen (Column 5, lines 14-27).

Regarding Claim 13, Nova et al. disclose the device wherein the machine-readable information is optically readable (Column 9, lines 3-13).

Regarding Claim 18, Nova et al. disclose the device further comprising additional information in a barcode format (Column 39, lines 39-56).

Regarding Claim 19, Nova et al. disclose the device wherein the bar code reader is one-dimensional bar code reader (Column 41, lines 5-13 and 29-44).

Regarding Claim 20, Nova et al. disclose the device wherein the bar code reader is two-dimensional bar code reader (Column 41, lines 5-13 and 29-44).

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Regarding Claim 21, Nova et al. disclose the device wherein the machine-readable information is magnetically readable (Column 41, lines 45-47).

Regarding Claim 22, Nova et al. disclose the device wherein the machine-readable information is electrically readable (Column 73, lines 45-50).

Regarding Claim 23, Nova et al. disclose the device further comprising human readable information i.e. orientation indicators (Column 43, lines 20-29).

Regarding Claim 24, Nova et al. disclose the device wherein the attached molecular moieties are protected i.e. screen or mesh (Column 42, lines 46-49 and 61-64).

Regarding Claim 25, Nova et al. disclose the device further comprising a protective layer over the molecular moieties i.e. screen or mesh (Column 42, lines 46-49 and 61-64).

Regarding Claim 26, Nova et al. disclose the protective layer is removable i.e. screen or mesh (Column 42, lines 46-49 and 61-64).

Regarding Claims 27, Nova et al. disclose the device further comprising a protective layer over the molecular moieties wherein the protective layer is composed of a material that allows only selected matter to be transmitted there through i.e. screen or mesh (Column 42, lines 46-49 and 61-64). The functional language "allows only selected matter to be transmitted there through" does not further limit the structural components of the device. Therefore, Nova et al. disclose the device as claimed.

Regarding Claim 30, Nova et al. disclose the device wherein the moieties comprise an array of biomolecules (Column 98, lines 30-60).

Regarding Claim 31, Nova et al. disclose the device wherein the biomolecules are nucleotidic (Column 98, lines 30-60).

Regarding Claim 32, Nova et al. disclose the device wherein the biomolecules are oligomeric (Column 98, lines 30-60).

Regarding Claim 37, Nova et al. disclose the device wherein the substrate comprises a disk i.e. silicon chip (Column 19, line 41-Column 20, line 1).

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Regarding Claim 39, Nova et al. disclose the device wherein the substrate comprises a well plate (Column 19, line 41-Column 20, line 1).

Regarding Claim 40, Nova et al. disclose the device wherein the substrate comprises a glass slide (Column 19, line 41-Column 20, line 1).

Regarding Claim 42, Nova et al. disclose the device wherein the substrate comprises a magnetic medium (Column 57, lines 14-27).

Regarding Claim 43, Nova et al. disclose the device wherein the substrate comprises an optical medium (Column 57, lines 14-27).

Regarding Claim 44, Nova et al. disclose the device wherein the surface having moieties attached thereto opposes a surface on which the information is located (Column 42, lines 42-45 and Fig. 25).

Regarding Claim 91, Nova et al. disclose the device wherein the information is in a discrete region from the surface having the moieties (Column 42, lines 42-45).

Regarding Claim 93, Nova et al. disclose the device wherein the machine readable information is located on a surface of the substrate that is noncoplanar with respect to the surface adapted for attachment to a plurality of moieties (Column 42, lines 42-45).

Regarding Claim 94, Nova et al. disclose the device wherein the machine readable information is moveable with respect to the substrate surface (Column 7, lines 50-65).

Regarding Claim 95, Nova et al. disclose the device wherein the substrate comprises a cartridge (Column 42, lines 33-67 and Fig. 23-27).

Regarding Claim 103, Nova et al. are silent regarding the substrate containing no less than 1 kilobyte of machine readable information. However, machine readable disk substrates comprising no less than 1 kilobyte of data were well known in the art at the time the claimed invention was made as taught by Virtanen (Column 4, lines 13-35) who teaches that the disk device provides for high density information and analyte detection utilizing disk readers known in the art (Column 5, lines 14-27 and Fig. 11). It would have been obvious to one of

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ordinary skill in the art at the time the claimed invention was made to apply the more than one kilobyte of data taught by Virtanen to the disk of Nova et al for the obvious benefits of providing a large amount of data readable utilizing readily available disk readers as taught by Virtanen (Column 5, lines 14-27).

### **Response to Arguments**

9. Applicant asserts that Virtanen does not teach Claim 1 as amended. Applicant further asserts that Claim 1 has been amended to incorporate the limitations of previous Claim 108 which, Applicant asserts was not rejected. Applicant's assertions are noted. However, Claim 108 was previously rejected. While the limitations of Claim 108 are incorporated into Claim 1, numerous additional limitations have also been added to claim 1 e.g. fluidic device, apparatus for measuring characteristics, machine for reading and commanding the device and etc. Therefore, the amendments introduce numerous limitations not previously considered or rejected.

Applicant asserts that Claim 3 is drawn to "secured" information, which Applicant interprets as information that is being kept secure e.g. by encryption and this is not taught by Virtanen or Hammock. The assertion is noted but is not found persuasive. The claimed "secured" information is given its broadest reasonable interpretation in view of the claim and specification which do not define "secured". As such, the phrase encompasses structural attachment of the information to the surface. Applicant points to the specification wherein the "smart card" embodiment is described to define the claimed "secured". However, the claim is not limited to a smart card. Therefore, the argument and citation are not commensurate in scope with the claim.

Applicant acknowledges that Virtanen discloses fluorescence detection means, but asserts that Virtanen does not teach machine-readable fluorescence. Applicant's argument has been considered but is not found persuasive because, as Applicant notes, Virtanen does teach



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reading fluorescence and uses a machine to do so (Column 38, line 65-Column 40, line 58). It is noted that the information detected by Virtanen is the target. However, the specification defines the claimed information at page 13, second paragraph: "The term "machine-readable information" as used herein refers to data, instructions, details, and other matter having a format that can be read by a machine." Given this broad definition of machine readable information, the fluorescently readable targets of Virtanen are encompassed by the claims.

Applicant traverses the Office's interpretation of "encased" and asserts that the screen or mesh cover of Nova does not encase as claimed. Applicant's arguments have been considered but are not found persuasive because the screen/mesh of Nova clearly covers the probes within the cavity thereby encasing the probes in the cavity (Column 42, lines 61-64) thereby meeting the limitations of the claim.

Applicant traverses the Office's interpretation of "removable" stating that as interpreted any covering would be removable. Applicant's traversal is noted. It is maintained that the term "removable" does not define the covering layer of that taught in the art, because the claim does not describe any structural limitations defining removable.

Applicant asserts that the densities of Hammock are not encompassed by the claimed 1,000,000/cm<sup>2</sup>. Applicant acknowledges that Hammock teaches features arrayed at a density of 10,000/cm<sup>2</sup>, but not the claimed 1,000,000/cm<sup>2</sup>. Applicant's arguments have been considered but are not found persuasive because, as noted by Applicant, Hammock teaches features at a density of 10,000/cm<sup>2</sup>, wherein each feature comprises a solution of molecules at concentration correlated with that of the analyte (Column 5, lines 65-67) wherein they exemplify analyte concentration 100uM (Example 3, line 47). As such, each feature of Hammock contains a large number of molecules. The claims are drawn to moieties per cm<sup>2</sup>. The 10,000/cm<sup>2</sup>, features comprising a large number of molecules are clearly encompassed by the claimed moieties.

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10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

#### **Conclusion**

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

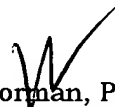
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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BJ Forman, Ph.D.  
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Art Unit: 1634  
June 29, 2005